

EXHIBIT 229

**MODEL LETTER ANNOUNCING TO THE CLIA-EXEMPT LABORATORY
THAT CMS WILL SEEK A TEMPORARY INJUNCTION
OR RESTRAINING ORDER**

(Date)

Director Name
Laboratory Name
Address
City, State, ZIP Code

Dear **(Director Name)**

Re: CLIA Number **(CLIA Number)**

Section 353(j) of the Public Health Service Act and implementing regulations specify that if the Secretary has reason to believe that the continuation of any activity by a laboratory would constitute a significant hazard to the public health, the Secretary may bring suit in U.S. District Court to enjoin continuation of the specific activity or, if necessary, to enjoin the continued operation of the laboratory.

A survey was conducted at **(name of laboratory)** on **(date)**. At the conclusion of this survey the findings were discussed with **(you or director's name)** and **(you, he, she)** was informed that the Conditions within **(name of laboratory)** pose a significant hazard to the public health. Specifically, the laboratory does not meet the following Clinical Laboratory Improvement Amendments (CLIA) Condition(s) and/or standards:

(Cite condition(s) and/or standard(s)).

We have enclosed a complete listing (Form CMS-2567, Statement of Deficiencies and Plan of Correction) of all deficiencies found by the Centers for Medicare & Medicaid Services (CMS) surveyors.

We informed the **(name of State)** on **(date)** of these deficiencies. However, because the **(name of State)** failed to take the appropriate enforcement action against your laboratory, CMS has filed suit in the U.S. District Court for the district in which your laboratory is located to enjoin the continued operation of the **(name of laboratory)**. This action can only be averted by correction of the deficiencies that caused the significant hazard to the public health.

If you have corrected these deficiencies, please advise us immediately to permit verification of the necessary corrections.

(Name)

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(Date)

The results of this survey will be made available to the public in accordance with the Federal Freedom of Information disclosure requirements.

A copy of this letter is being forwarded to the (State).

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure(s)

cc: Central Office